UNITED STATES DISTRICT COURT OF THE SOUTHERN DISTRICT OF WEST VIRGINIA CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY LITIGATION

MDL Case No.: 2:08-md-1968

THIS DOCUMENT RELATES TO:
McCornack v. Actavis, 09-cv-0671
Vega v. Actavis, 09-cv-0768

PLAINTIFFS' POST-HEARING BRIEF

This brief succinctly highlights some of the evidence (and citations) confirming Dr. Bliesner's conclusion in his expert report and declaration (Pl. Ex. 500 and 620) that double-thick or excess-strength Digitek tablets reached the market, and confirming that Mr. McCornack's ingestion of such defective excess-strength Digitek caused his death. There are not merely triable issues of fact in these respects, but abundant and persuasive evidence.

First, there are several documented incidents of defective out-of-specification size/weight Digitek ***actually found in the market***, including:

- June 8, 2004: Rite-Aid pharmacist finds a double-thick/double-weight Digitek tablet. Pl. Exs. 128, (Bates 338-42); Pl. Ex. 241, (Bates 599); Pl. Ex. 242, (Bates 601).
- March 18, 2008: Actavis distributor, UDL, reports consumer complaining of a "thin" tablet and that "her heart was racing." Pl. Ex. M69, (Bates 660).
- April 2008: Licensed nurse and clinical support consultant hired to inspect a nursing facility's in-stock Digitek in connection with the April 2008 recall discovers packaged double-thick tablet. PACER Docket No. 562-1 and 527-1.
- Jan. 2009: Actavis confirms nine complaints of double-thick Digitek tablets during a six-month period from August 2008 to January 2009. Pl. Ex. 73, (Bates 109).

Second, there are repeated instances of ***packaged*** defective out-of-specification size/ weight Digitek only fortuitously discovered prior to release:

- Nov. 30, 2007: Twenty double-thick Digitek tablets discovered, including several already packaged or at packaging stage. Line worker happens to notice two double-thick tablets moving through packaging machinery. Pl. Ex. 16, (Bates 4-6).
- Jan. 2008: Actavis distributor, Mylan, identifies two batches of Digitek with out-of-specification assays (too low). Pl. Ex. M14, (Bates 626).
- April 1, 2008: Several 5,000 count tablet bottles at the end of a batch found in excess of weight specifications. In one, 17 out of 50 tablets are 10-20% above weight specifications. The problem is only revealed because so many tablets were defective that weighing an entire 5,000 tablet bottle sufficed to detect the excess product weight. Pl. Ex. 141, (Bates 353).

Third, additional evidence further confirms Actavis' chronic inability to prevent deviations from product weight/size specifications, and the company's concomitant concealment of the true frequency of such deviations:

- Dec. 1990: Recall for variation in tablet size and strength. Pl. Ex. M45, (Bates 638).
- March 1994: Loss of active ingredient discovered during blending/compression, without explanation or concern on Actavis' part. Pl. Ex. 500 (A4), (Bates 687).
- Oct. – Nov. 2001: Thin (sub-strength) tablets discovered during packaging. Although finding 1,600 thin tablets in four drums, inspection is not extended to several other drums from that same batch. Pl. Ex. 236, (Bates 594).
- July – Aug. 2006: FDA finds that Actavis fails to document all of its manufacturing deviations. Pl. Ex. 90, (Bates 208 *et seq.*).

- Jan. – Jun. 2007: Two 2007 Digitek batches found with blend uniformity failures (part of a larger blending failure also affecting 17 batches of other Actavis products); one is released. Pl. Ex. 183, (Bates 470-71).
- May 22, 2007: 2005 Digitek found out-of-spec for weight. Pl. Ex. 501, (Bates 777).
- Late 2007: Unexplained blend failure for two Digitek batches; both released. Pl. Ex. 159, (Bates 419-420).
- Feb. 2008: Multiple sub-thickness Digitek tablets found. Pl. Ex. 217, (Bates 515).

Fourth, Actavis's routine release of suspect product, (even after actual deviations from specifications have been detected), without adequate investigation:

- Early 2007: Despite finding two Digitek batches with blend uniformity failures, (part of a larger blend failure also affecting 17 batches of other Actavis products); one is released. Pl. Ex. 183, (Bates 470-71).
- Nov. 2007: Despite finding 20 double-thick Digitek tablets in a single batch after a visual inspection, Actavis decides to release the batch, so long as no more than one additional defective tablet is found out of a 1,330 tablet sample. Pl. Ex. 16, (Bates 61.) The vice-president of quality control described this as the "accept on 1, reject on 2 (total for batch)" policy when out-of-specification tablets are discovered. Ibid. Even in this context, (a supposedly "high level tightened AQL inspection" of a batch known to defective), Actavis deems 1 in 1,330 an acceptable defect rate.[1] The 20 defective tablets were destroyed, and the remainder of the batch

[1] *See also*, Pl. Ex. 503, (Lambridis Depo, Bates No. 1062, 1076-77, 1079-80, Actavis's vice-president of quality control, admitting that Actavis had no further QC procedures, beyond releasing the product, had one additional defective tablet been found). The subject batch was approximately 4.7 million tablets (Pl. Ex. 16, Bates 61) and a single year's Digitek production is approximately 184 million tablets (Pl. Ex. 253, Bates 610-11). Considered in this framework, the 1 in 1,330 defect rate accepted by Actavis would represent more than 3,000 defective tablets per batch and more than 138,000 defective tablets per year of production.

released despite the VP for quality control's concession that additional testing (such as blend uniformity or weight) might well have identified additional defective tablets. Pl. Ex. 503, (Lambridis Depo., Bates No. 921). The cause of the defective double-thickness tablets was never determined. Pl. Ex. 503, (Lambridis Depo., Bates 916-917).

- Mar. – May 2008: FDA notes that Actavis routinely releases product (including Digitek), even after discovery of tablet size/strength deviations, without completing an adequate investigation, or investigating other contemporaneous batches. Pl. Ex. 91, (Bates 227).
- April 17, 2008: Actavis internally predicts potential regulatory problems from its release of out-of-specification product, release of product prior to completing deviation investigations, and partial lot releases of Digitek despite finding "a toxic product with double, triple, and thin tablets." Pl. Ex. 146, (Bates 371-72).

Fifth, the 2008 nationwide products recalls (and the undeniable financial impact on Actavis). Initially limited to a particular batch, the nationwide Digitek recall was quickly expanded to all Digitek batches within its expiry. Pl. Ex. 503, (Lambridis Depo., Bates No. 923-929). The recall notices and press releases specifically admitted the possible release of double-strength Digitek. *See, e.g.*, Pl. Ex. 505, (Bates 1218); Pl. Ex. 504, (Bates 1195); Pl. Ex. 506, (Bates 1222). It stretches credulity to argue that such an expensive recall was initiated without defective product reaching the market. This is even less persuasive when considering the expansion of the product recall to include 66 other Actavis products. Pl. Ex. 500, (A63).

Sixth, Mr. McCornack's significantly elevated digoxin blood level (Pl. Ex. 602.5, (Bates 10292-93)) confirms his ingestion of defective Digitek. For several years, Mr. McCornack had taken Digitek (and before that other digoxin products) without any significant fluctuation in his consistent, therapeutic blood level. Pl. Ex. 600, (*Von Dollen Depo.*, 86:19-25); Pl. Ex. 601,

(*Lemm Depo.*, 65:6-9, 54:23-55:6, 43:11-44:12, 54:23-55:6, 68:25-69:7, 90:4-11); Pl. Ex. 613, (*Heard Depo.*, 44:20-41:2). He was responsible and compliant with his medication regimen, and utilized a pill organizer to this end. Pl. Ex. 600, (*Von Dollen Depo.*, 95:9-14, 57:17-60:5); Pl. Ex. 601, (*Lemm Depo.*, 79:22-24, 90:12-17); Pl. Ex. 602.1 and Pl. Ex. 609, (*K. McCornack Depo.*, 60:9-61:13). The coroner/pathologist, treating physicians, and expert pharmacologist Mr. Gibson, all could find no other legitimate explanation for the degree of this sudden digoxin blood level increase.[2] *See citations below*, and Pl. Ex. 607, (Gibson Report, Bates 11436-44).

Seventh, every non-retained physician who has evaluated Mr. McCornack – the coroner/pathologist, his treating cardiologist, and his primary treating physician – has concluded that he died of digoxin poisoning. Pl. Ex. 602.5 (Autopsy Report); Pl. Ex. 603, (*Mason Depo. II*) and Pl. Ex. 602, (*Mason Depo. I*); Pl. Ex. 600, (*Von Dollen Depo.*); Pl. Ex. 601, (*Lemm Depo.*) Prior to his death, Mr. McCornack's condition was decidedly benign and well-controlled. *See, e.g.*, Pl. Ex. 600, (*Von Dollen Depo.*, 43:7-45: 21, 47:7-16, 72:12-75:11, 95:6-8). At his very recent doctor's exams, there had been no signs of any change in condition or of any digoxin toxicity. Pl. Ex. 601, (*Lemm Depo.*, 33:18-34:1). Not coincidentally, Mr. McCornack died at the moment of peak digoxin effect. Pl. Ex. 607, (Gibson Report, Bates 11439, 11444).

Dated: September 20, 2011

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[2] Mr. McCornack's elevated digoxin level while taking Digitek is not an isolated incident. For example, the 17 Adverse Drug Events for Digitek in 2006 included unexpectedly elevated digoxin blood levels, a "potency question," and other digoxin toxicity type symptoms. Pl. Ex. 253, (Bates 613-14).

CERTIFICATE OF SERVICE

I hereby certify that on September 20, 2011, I electronically filed the foregoing document with the Clerk of Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

Dated: September 20, 2011

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